

Appl. No. 10/803,126  
Docket No. 9183M&  
Amdt. dated February 12, 2007  
Reply to Office Action mailed on August 10, 2006  
Customer No. 27752

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### REMARKS

#### Claim Status

Claims 1-9, 11, 12 and 14-25 were examined. Claims 1, 8, 18 and 22 are amended, Claims 5-7, 10 and 13 are canceled and Claims 26 and 27 are added herein. Accordingly, Claims 1-4, 8-9, 11-12, and 14-27 are currently pending.

#### Remarks

Claim 1 has been amended to further define the present invention wherein the zinc containing layered material is a hydroxy-containing basic zinc carbonate. Support for this amendment is found in Claim 22, as originally filed.

Claim 8 has been amended to further define the stoichiometry of basic zinc carbonate. Support for this amendment is found on page 5, lines 18-20.

Claim 18 has been amended to further clarify that the basic zinc carbonate contains hydroxy groups. Support for this amendment can be found at least at page 5, lines 18-10 of the present specification.

Claim 22 has been amended to further define a process for preparing a personal care composition that includes basic zinc carbonate containing hydroxy groups, wherein the basic zinc carbonate is present in an amount from about 0.001 to about 10% weight % based on the total weight of the composition. Support for this amendment can be found at least at page 4, lines 12-15.

New Claim 26 has been added to further define a process for preparing a personal care composition wherein the basic zinc carbonate is present in an amount from about 0.01% to about 7% weight%, based on the total amount of the composition. Support for this amendment is found on page 4, lines 12-15.

New Claim 27 has been added to further define a process for preparing a personal care composition wherein the basic zinc carbonate is present in an amount from about 0.1 weight% to about 5 weight %, based on the total amount of the composition. Support for this amendment is found on page 4, lines 12-15.

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No new matter is added herein. Consequently, entry of these changes is believed to be in order and is respectfully requested.

**Rejection Under 35 USC §102(b) Over WO 01/00151 (Gavin et al.)**

Claims 1-19, 11, 12, 14-17 and 23-25 have been rejected under 35 USC §102(b) as being anticipated by International Patent Application No. WO 01/00151 to Gavin, et al (hereinafter "Gavin et al.").

Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, the composition of Gavin, et al. includes from about 0.001% to about 10% by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione, from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts and mixtures thereof and a topical carrier for the anti-microbial active and the metal salt.

Gavin et al. discloses a myriad of zinc salts, including zinc carbonate and a dozen or so other zinc salts at page 6, lines 1-6 of the reference. In this long list of zinc salts, there is no disclosure or suggestions of a hydroxy-containing basic zinc carbonate.

In contrast, Claim 1 and the claims dependent therefrom are directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc layered material is hydroxy-containing basic zinc carbonate.

The Office Action asserts that the claimed augmentation factor is inherently disclosed in Gavin et al. However, Gavin et al. does not disclose or suggest any hydroxy-containing basic zinc carbonate, and therefore cannot inherently disclose any zinc-containing layered material containing it, much less one having an augmentation factor as instantly claimed.

The Office Action asserts that "zinc carbonate" is synonymous with "basic zinc carbonate" as defined in the instant specification. However, it is respectfully submitted that the specification at page 5, lines 25-26 merely discloses that the terms are used interchangeably in commercial product designations.

As support for the interchangeability of the terms "zinc carbonate" and "basic zinc carbonate", the outstanding office action points to an MSDS sheet from Mallinckrodt Baker, Inc. However, this MSDS sheet is not properly considerable as art as of the filing

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date of the instant application since the face of the MSDS sheet shows a publication date of 2006. Further, the MSDS sheet itself presents inconsistent information. Although the chemical formula presented in the MSDS sheet shows hydroxyls present, the "Composition/Information on Ingredients" does not identify any hydroxyls. Further, the "Composition/Information on Ingredients" identifies the presence of a major amount of Zinc Oxide (70%) in the zinc carbonate product being described by the MSDS sheet. To the contrary, zinc carbonate does not comprise zinc oxide.

Applicants do not concede that the term zinc carbonate is synonymous with basic zinc carbonate. Instead, Applicants respectfully summarizes the inconsistencies reflected in the 2006 MSDS sheet:

- Firstly, the title of the MSDS is Zinc Carbonate. The chemical formula of zinc carbonate is identified as  $3\text{Zn}(\text{OH})_2 \cdot 2\text{ZnCO}_3$ . As Applicants have shown in the 1.132 Declaration of James R. Schwartz submitted June 1, 2006, the recognized formula for Zinc Carbonate is  $\text{ZnCO}_3$ . The formula for basic zinc carbonate is  $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2$ . As shown by the chemical formulas, Applicants submit basic zinc carbonate contains at least one "-OH" group, while zinc carbonate does not contain any "-OH" groups. As the MSDS does not have the correct chemical formula for zinc carbonate, Applicants submit the MSDS is erroneous. The MSDS purports to identify and provide information concerning "zinc carbonate". Accordingly, the MSDS should contain the correct formula of zinc carbonate, which is  $\text{ZnCO}_3$ .
- Secondly, Section 2 of the MSDS, entitled "Composition/Information on Ingredients" states the Ingredients of Zinc Carbonate are Zinc Carbonate (3%) and Zinc Oxide (70%). Zinc Carbonate, having the correct formula of  $\text{ZnCO}_3$ , does not contain Zinc Oxide. Therefore, this MSDS is internally inconsistent with regard to nomenclature. The chemical formula and the list of ingredients for the purported "Zinc Carbonate" of the MSDS are not consistent with each other.

Additionally, in view of the late date of the MSDS sheet vis-a-vis the filing date of the instant application, and in view of the inconsistencies in the data presented in the MSDS sheet, it is respectfully submitted that it cannot be relied upon to provide any expanded scope to the disclosures to the Gavin et al. reference beyond that reflected in the Gavin et al. reference itself.

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In short, Applicants maintain that personal care compositions comprising hydroxy-containing basic zinc carbonate as instantly claimed are neither disclosed nor suggested by the disclosure of zinc carbonate provided among a myriad of zinc salts alluded to in Gavin et al. This is evidenced in the 1.132 Declaration previously submitted.

As noted in our discussion above and shown in the previously submitted 1.132 Declaration, basic zinc carbonate contains an "-OH" group. In contrast, zinc carbonate, as shown above, does not contain an "-OH" group. There is no discussion in Gavin et al. to alter the zinc carbonate by introduction of an "-OH" group, as there is no hydroxide, hydroxyl or hydroxy terms disclosed or taught. Clearly, had Gavin et al. been showing any intention to use any and all variants of zinc carbonate, such disclosure would be found.

As previously explained in the 1.132 Declaration, zinc carbonate is structurally different from basic zinc carbonate. Accordingly, the composition of the instantly claimed invention is not the same as the composition of Gavin et al. Therefore, the composition of Gavin et al. would not inherently have an augmentation factor of greater than 1, as is recited in the instant claims.

When one of ordinary skill in the art compares the composition of Gavin et al. to the instantly claimed invention, the compositions are not comprised of the exact same materials; namely Gavin et al. does not teach or suggest a hydroxy-containing basic zinc-carbonate personal care composition and would not inherently have the exact same properties as the currently claimed product.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

**Rejection Under 35 USC §102(b) Over US 4,943,432 (Biener)**

Claim 22 has been rejected under 35 USC §102(b) as being anticipated by US 4,943,432 to Biener (hereinafter "Biener").

Biener discloses a composition for the treatment of psoriasis and other skin diseases. The composition is composed primarily of a mixture of magnesium halide, such as magnesium chloride, with mixed alkali and alkaline earth metal salts such as sodium and potassium chloride and/or bromide and calcium chloride or bromide. Other cations present in the composition include: strontium, aluminum, iron, lithium, and zinc. Anions present in the compound include: sulphate, hydrogen carbonate, borate, fluoride, silicate,

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iodide and carbonate. The salt mixture was made to duplicate the components found in the water of the Dead Sea.

In contrast, Claim 22 is directed to a process for preparing a personal care composition comprising hydroxy-containing basic zinc carbonate. The process includes reacting a carbonate or bicarbonate salt with a zinc compound causing in-situ reaction of the carbonate salt with the zinc salt to form basic zinc carbonate.

While Biener does disclose a composition that contains carbonate and zinc, the composition contains a number of other components that may react with the zinc and carbonate to prevent, or impede, the formation of basic zinc carbonate. There is no suggestion in Biener that the components of the composition react to form basic zinc carbonate in situ.

Additionally Claim 22 is amended to further clarify the amount of basic zinc carbonate present in the composition. Specifically, Claim 22 has been amended to require basic zinc carbonate in an amount within a range that is neither disclosed nor suggested by a composition containing, for example, one molecule of basic zinc carbonate that the Office Action postulates might form in the composition disclosed in Biener. In reciting ranges having even higher thresholds of basic zinc carbonate, Claims 26 and 27 further distinguish over any minute amount of basic zinc carbonate postulated to form in the composition of Biener.

Applicants submit the disclosure of Biener does not teach or suggest the formation of basic zinc carbonate, much less teach or suggest the claimed amount of the basic zinc carbonate.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

**Rejection Under 35 USC §102(b) Over US 4,933,101 (Cilley et al.)**

Claim 22 has been rejected under 35 USC §102(b) as being anticipated by US 4,933,101 to Cilley et al. (hereinafter "Cilley et al.").

Cilley et al. discloses liquid automatic dishwashing detergent compositions containing an insoluble zinc salt useful for inhibition of glassware corrosion in the dishwasher. The Office Action states that Cilley et al. discloses a detergent composition comprising sodium carbonate and zinc oxide (Column 22, lines 1-23). The Office Action further states that Cilley et al. provides methods of making the composition, which comprises paddling the zinc oxide into a pre-mixed sodium carbonate containing mixture (Column 22, lines 25-44). The Office Action asserts that since the components are the

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same in the Cilley et al. disclosure as the instantly claimed composition than it would have formed basic zinc carbonate in-situ and anticipates the instant invention.

Zinc carbonate and basic zinc carbonate are disclosed in Cilley et al at Column 22, line 54. Cilley et al. recognizes that zinc carbonate and basic zinc carbonate are different compounds and the terms are not synonymous since it discloses both zinc carbonate and basic zinc carbonate as two separate insoluble inorganic zinc salts. Cilley et al. only exemplifies zinc carbonate in Example IV (Column 23, lines 13-14).

Currently amended Claim 22 is drawn to a process for preparing a personal care composition comprising hydroxy-containing basic zinc carbonate wherein the basic zinc carbonate is present in an amount from about 0.001% to about 10% based on the total weight of the composition. Cilley et al. does not disclose or suggest a process for preparing a basic zinc carbonate-containing composition, much less a composition containing any amount of basic zinc carbonate within the instantly-claimed range.

Further, Cilley et al. focuses on silicate chemistry. This is demonstrated in all of the examples, which all require silicates. There is no motivation to alter the silicate chemistry taught in Cilley et al. to obtain the currently claimed process.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

**Rejection Under 35 USC §103(a) over US 4,161,526 (Gorman) in view of US 3,960,782 (Daley)**

Claims 18-21 have been rejected under 35 USC §103(a) as being unpatentable over US 4,161,526 to Gorman (hereinafter "Gorman") in view of US 3,960,782 to Daley (hereinafter "Daley").

In order to establish a prima facie cast of obviousness, the Examiner must show that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there is a reasonable expectation of success, and (3) all of the limitations of the claims are taught or suggested in the prior art (M.P.E.P. 2143).

Gorman discloses pyrithione, pyrithione or dipyrithione compositions containing the zinc salt of an organic or an inorganic acid, zinc hydroxide or zinc oxide or a mixture thereof for the prevention or removal of discoloration in the compositions. As stated in the Office Action, Gorman does not expressly disclose the addition of a

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bicarbonate/carbonate salt to the composition that would react in-situ with the zinc salt to produce basic zinc carbonate with a range of between about 1:10 to about 10:1.

Daley discloses shampoo compositions which impart luster and manageability to hair. The compositions comprise an alkyl sulfate or alkyl monoglyceride sulfonate surfactant, urea, dodecyl alcohol and guanidine or a water-soluble salt thereof. The compositions have a pH or from about 5 to about 8. The Office action asserts that it would have been obvious to one of skill in the art to modify the composition of Gorman by adding sodium carbonate as suggested by Daley et al. to produce the instant invention. The Office action further asserts that one of skill in the art would have been motivated to do this because Daley et al. discloses that sodium carbonate is a conventional pH adjusting reagent in shampoo compositions.

In contrast, Claim 18, and the claims dependent therefrom, relate to a process for preparing a personal care composition comprising hydroxy-containing basic zinc carbonate. The process includes reacting a carbonate or bicarbonate salt that is soluble in the personal care composition with a zinc compound that is soluble or insoluble in the personal care composition. The reaction causes in-situ formation of the carbonate salt with the zinc salt to form basic zinc carbonate in the personal care composition. As recited in dependent Claim 19, the zinc hydroxide is reacted with the sodium carbonate in a molar ratio within a range of between about 1:10 and about 10:1.

Neither Gorman nor Daley et al. disclose or suggest a personal care composition comprising hydroxy-containing basic zinc carbonate much less a process for reacting a carbonate or bicarbonate salt that is soluble in the personal care composition with a zinc compound to form basic zinc carbonate in situ. Furthermore, Applicants submit that one of ordinary skill in the art would not combine Gorman and Daley for any reason. According to Gorman, there was a problem with the discoloration of pyrithione that lead to consumer dissatisfaction and economic loss (see Col. 1, lines 24-28). To overcome this discoloration problem, Gorman added from about 0.01 percent to about 1 percent of the zinc salt of an organic or inorganic acid, zinc hydroxide or zinc oxide or a mixture thereof. (see Col. 1, lines 50-55). In contrast, Daley et al. sought to develop a product that imparts outstanding luster and manageability to hair (see Col. 1, lines 13-16). Daley et al. purported to achieve this product by utilizing a combination of ingredients that included: a surfactant, urea, a water-soluble guanidine salt and dodecyl alcohol (see Col. 1, lines 50-60). Daley et al. specifically teaches that sodium carbonate is a conventional pH adjusting agent. (Column 3, lines 23-25) Applicants submit that one of ordinary skill

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in the art recognizes that sodium carbonate does not provide hair luster and manageability benefits.

Applicants submit one of ordinary skill in the art would not modify Gorman who sought to improve the discoloration of pyrithione, with the teaching of Daley et al. Specifically, one of ordinary skill in the art has no motivation to combine the teaching of Gorman with the teaching of Daley et al., since both references seek to solve two separate and distinct problems, i.e. one reference purports to solve a problem associated with the color of a pyrithione product, while the other reference seeks to improve the function of a shampoo. Therefore, there is no motivation to combine the teachings of Gorman with the teaching of Daley et al.

Inasmuch as a prima facie case of obviousness has not been established, Applicants respectfully request the Examiner withdraw this rejection.

#### **The Double Patenting Rejection**

I. Claims 1, 5-9, and 23-25 are provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-3, 5, 14-17 and 23-24 of copending Application No. 10/802,166.

Claim 1 of Application 10/802,166 is directed to a composition comprising from about 0.001% to about 10% of a zinc-containing layered material; from about 2% to about 50% of a surfactant including a surfactant with an anionic functional group; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

In contrast, the instant invention is directed to a composition comprising from about 0.01 weight% to about 5 weight%, based on the total weight of the composition, of pyrithione or a polyvalent metal salt of a pyrithione; from about 0.001 weight% to about 10 weight%, based on the total weight of the composition, of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc-containing layered material comprises hydroxy-containing basic zinc carbonate.

The currently claimed invention is not directed to or required to have a relative zinc lability of greater than about 15% for a zinc-containing layered material. Further, the '166 composition is not directed to or required to have a composition containing an augmentation factor greater than 1. These 2 claim sets are patentable distinct and each of the specification and data demonstrate that the determination of an augmentation factor



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or relative zinc lability is not a matter of routine optimization. Augmentation and Relative Zinc lability are two distinct components. An "augmentation factor" is defined, which is the ratio of the MIC (minimum inhibitory concentration) with and without an augmenting agent (at a specified concentration) (Page 28, lines 14-16 of the instant application). Whereas "zinc lability" is a measure of the chemical availability of zinc ions. Soluble zinc salts that do not complex with other species in solution have a relative zinc lability, by definition, of 100%. The use of partial soluble forms of zinc salts and/or incorporation in a matrix with potential complexants generally lowers the zinc lability substantially below the defined 100% maximum (page 30, lines 11 - page 31, lines 1-9 of the '166 application). Therefore, Augmentation and Relative Zinc Lability are two patentably distinct components. And the instant claims and those of copending Application 10/802,166 are patentably distinct.

Applicants respectfully request reconsideration and withdrawal of this nonstatutory obviousness-type double patenting.

#### Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC § 102 and 103. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-4, 8-9, 11-12, and 14-27 is requested.

Respectfully submitted,  
THE PROCTER & GAMBLE COMPANY  
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